

CLAIMS

What is claimed is:

- 5 1. A heterogeneous pharmaceutical composition comprising two different therapeutically active agents in effective amounts, said therapeutically active agents comprising:
 - a. a carboxylic acid, or a salt or ester thereof; and
 - b. a peroxide;
- 10 wherein a multiplicity of solid particles comprises one therapeutically active agent such that the other therapeutically active agent is effectively excluded from said particles and wherein said composition is useful for treating acne.
- 15 2. The composition of claim 1 wherein said carboxylic acid, or salt or ester thereof comprises azelaic acid, or a salt or ester thereof.
3. The composition of claim 1 wherein said carboxylic acid, or salt or ester thereof comprises salicylic acid, or a salt or ester thereof.
4. The composition of claim 1 wherein said carboxylic acid, or salt or ester thereof comprises azelaic acid.
- 20 5. The composition of claim 1 wherein said peroxide is hydrogen peroxide.
6. The composition of claim 1 wherein said peroxide is benzoyl peroxide.
7. The composition of claim 1 wherein said multiplicity of solid
- 25 particles has an average particle diameter of from 0.1 mm to 1 mm.
8. The composition of claim 7 wherein no particle of said multiplicity of solid particles has a diameter larger than 1 mm.
9. The composition of claim 1 wherein said multiplicity of solid
- 30 particles comprises a material selected from the group consisting of beeswax, Jojoba oil, coconut oil, methyl stearate, paraffin wax, and mixtures thereof.

10. The composition of claim 1 wherein the multiplicity of solid particles has a melting point of less than 100 °C.
11. The composition of claim 1 wherein the multiplicity of solid particles has a melting point greater than 20 °C.
- 5 12. The composition of claim 1 wherein the multiplicity of solid particles has a melting point from 30°C to 70 °C.
13. The composition of claim 1 wherein the multiplicity of solid particles has a melting point from 35 °C to 50 °C.
14. The composition of claim 1 wherein the multiplicity of solid particles has a melting point from 35°C to 42 °C.
- 10 15. The composition of claim 1 wherein the multiplicity of solid particles comprises the carboxylic acid, or a salt or an ester thereof.
16. The composition of claim 1 wherein the multiplicity of solid particles comprises said peroxide.
- 15 17. The composition of claim 1 wherein the carboxylic acid is azelaic acid which is comprised in the multiplicity of solid particles, said multiplicity of solid particles also comprising beeswax and Jojoba oil and having a melting point between 35-42 °C.
18. The composition of claim 17 wherein said multiplicity of solid particles has an average particle diameter of 0.1 mm to 1 mm, and wherein no particle of said multiplicity of solid particles has a diameter larger than 1 mm.
- 20 19. A method of preparing a pharmaceutical composition comprising
 - a. providing two therapeutically active agents in effective amounts, one therapeutically active agent being a carboxylic acid, or a salt or an ester thereof; and another therapeutically active agent being a peroxide;
 - 25 b. providing a multiplicity of solid particles comprising one of the two therapeutically active agents in a manner that substantially excludes contact between the two therapeutically active agents;
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- c. providing an aqueous liquid wherein said solid particles are dispersed said aqueous liquid phase;

wherein said composition is useful for the treatment of acne.

- 5 20. The method of claim 19 wherein said carboxylic acid, or salt or ester thereof comprises azelaic acid, or a salt or ester thereof.
21. The method of claim 19 wherein said carboxylic acid, or salt or ester thereof comprises salicylic acid, or a salt or an ester thereof.
22. The method of claim 19 wherein said carboxylic acid, or salt or ester thereof comprises azelaic acid.
- 10 23. The method of claim 19 wherein said peroxide is hydrogen peroxide.
24. The method of claim 19 wherein said peroxide is benzoyl peroxide.
- 15 25. A method of stabilizing a carboxylic acid, or a salt or ester thereof in a pharmaceutical product also comprising a peroxide, wherein said product is useful for the treatment of acne, comprising
- a. entrapping the carboxylic acid, or salt or ester thereof in a multiplicity of solid particles such that the peroxide is effectively excluded from said particles; or
 - 20 b. entrapping the peroxide in a number of solid particles such that the carboxylic acid, or salt or ester thereof is effectively excluded from said particles.
26. The method of claim 25 wherein said carboxylic acid, or salt or ester thereof comprises azelaic acid.
- 25 27. The method of claim 25 wherein said peroxide is benzoyl peroxide.
28. A pharmaceutical product comprising water, a multiplicity of solid particles, two therapeutically active agents, and a package wherein
- a. the first therapeutically active agent is a carboxylic acid, or a salt or an ester thereof; and
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- b. the second therapeutically active agent is a peroxide; and
c. one of the therapeutically active agents is entrapped in said multiplicity of solid particles such that contact between the therapeutically active agents is substantially reduced; and
5 d. the package is suitable for dispensing the therapeutically active agents and the product is indicated for the treatment of acne.
29. The product of claim 28 wherein said package has an opening for dispensing the product wherein no particle of said multiplicity of
10 particles is too large to fit through said package opening.
30. The product of claim 29 wherein said package has an opening for dispensing the product which has a diameter greater than 1 cm.
31. The product of claim 29 wherein said opening for dispensing the product has a diameter from 0.5 mm to 1 cm.
- 15 32. The product of claim 29 wherein said opening for dispensing the product has a diameter from 1 cm to 10 cm.
33. The composition of claim 1 which further comprises a viscosity enhancing agent.
34. The composition of claim 1 wherein the carboxylic acid, or salt or
20 ester thereof comprises tazarotene.
35. The product of claim 29 wherein the carboxylic acid, or salt or ester thereof comprises tazarotene.
36. The composition of claim 1 wherein the carboxylic acid, or salt or ester thereof is not a retinoid.
- 25 37. The product of claim 29 wherein the multiplicity of solid particles have a melting point from 31°C to 36°C.
38. The method of claim 25 wherein the carboxylic acid, or salt or ester thereof comprises tazarotene.